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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,073	09/08/2005	Venugopal K Nair	AM 101125	7581
25791	7590	08/19/2008		
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			EXAMINER HURT, SHARON L.	
			ART UNIT	PAPER NUMBER
			1648	
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			08/19/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/530,073

**Applicant(s)**

NAIR ET AL.

**Examiner**

SHARON HURT

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 10 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- \_\_\_\_\_ Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

The amendments to the claims filed December 7, 2007 have been acknowledged and entered. Claims 3, 7 and 9-12 are currently amended.

### ***Status of the Claims***

**Claims 1-14** are pending and under examination. Claims 15-21 have been canceled.

### ***Claim Objections***

The objection of claims 7-16 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim **is withdrawn**. Applicants have amended the claims to resolve the multiple dependent claims.

The objection of claims 9 and 10 because the claims were not labeled with sequence identifiers **is withdrawn**. Applicants have amended the claims with sequence identifiers to resolve the objection.

### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Davidson et al. **is withdrawn**. Applicant's arguments, filed December 7, 2007, have been fully considered and are persuasive.

The rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Handberg et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Handberg et al in view of Becker et al. **is withdrawn**. Applicant's arguments have been fully considered and are persuasive.

***New Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-5, 7-8 and 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Handberg** et al. (Avian Pathology, June 1, 2001, Vol. 30, No. 3, pages 243-249) in view of **Carrozza** et al. (Avian Diseases, Oct.-Dec. 1973, Vol. 17, No. 4, pages 767-781).

The claimed invention is drawn to a method of detecting a virus in an avian tissue sample comprising: extracting genetic material from an avian tissue sample; and testing for a virus; the avian tissue sample is from feathers, wherein the method provides quantitative information, wherein the virus is MDV, wherein the method is specific for MDV serotype 1 or MDV-1 Risps strain CVI 988.

The claimed invention is also drawn to a method, which comprises: (a) providing a polynucleotide sequence which is virus-specific; (b) a probe that specifically binds to its target virus; (c) determining the probe has bound with the target polynucleotide, by amplifying a region of the target polynucleotide; and (d) determining the presence of the target virus in the sample,

wherein the method is PCR, wherein the extracted genetic material is treated with agent to overcome inhibitory effect of the feather tissue, wherein the agent is bovine serum albumin, porcine albumin or ovine albumin.

Handberg et al. (hereinafter Handberg) teaches a method for detecting Marek's disease virus (MDV) by polymerase chain reaction (PCR) using various tissue samples from chickens, including feather tips conveniently collected in the field (Abstract). Handberg teaches the method is sensitive and specific for MDV serotype 1 including strain CVI988 (Abstract). PCR was performed on the purified DNA samples using two primer sets, oligonucleotides specific for MDV serotype 1 (page 245, Polymerase Chain Reaction). Handberg teaches all the limitations of the instant claimed invention. Handberg teaches the DNA extract were pre-treated with bovine serum albumen (BSA) to reduce the melanin inhibition effect (Abstract and page 248, 1<sup>st</sup> column, last full paragraph). Handberg also teaches MDV causes lymphoproliferative disease in chickens (page 243, 1<sup>st</sup> paragraph).

Handberg does not teach the feathers were from the axillary tract.

Carrozza et al. (hereinafter Carrozza) teaches MDV replicated in epithelial cells of feather follicles and these cells are the main source of infective virus and follicular epithelium has been established as the site of viral replication (page 768, 1<sup>st</sup> paragraph). Carrozza teaches a bioassay for the detection of MDV wherein skin from feathers from the axillary tract were tested by staining with fluorescent antibody (page 770).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to test skin from feather from the axillary tract because Carrozza teaches MDV is present in these feathers. The person of ordinary skill in the art would have

been motivated to use axillary tract feathers because Handberg teaches MDV affects the lymph nodes of chickens, and reasonably would have expected success because of the teachings of Handberg and Carrozza.

**Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Handberg et al. in view of Carrozza et al. as applied to claims 1-5, 7-8 and 12-14 above, and further in view of **Becker** et al. (Virus Genes, 1993, Vol. 7, No. 3, pages 277-287).

The claimed invention is drawn to the claimed invention described above wherein the method comprises providing a forward and reverse primers selected from the nucleotide sequence which flanks the 132 bp repeat nucleotide sequence of MDV; amplifying the sequence between the primers; detecting the number of repeats; and identifying the type of MDV in the sample.

The teachings of Handberg and Carrozza are described above. Neither Handberg nor Carrozza teach the 132 bp repeat sequences of MDV.

Becker et al. (hereinafter Becker) teaches a method of PCR detection of Marek's disease virus type 1 (MDV-1) that amplified MDV-1 (CVI 988, Rispens) DNA sequences containing the 132 bp repeats (Abstract).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to amplify the 132 bp repeat region in a PCR to detect MDV-1. The person of ordinary skill in the art would have been motivated to make that modification because Becker teaches MDV-1 (CVI 988, Rispens) contains multiple copies of 132 bp repeats (Abstract), and reasonably would have expected success because of the teachings of Handberg, Carrozza and Becker.

**Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Handberg et al. in view of Carrozza et al. as applied to claims 1-5, 7-8 and 12-14 above, and further in view of **Burgess et al.** (Journal of Virological Methods, Sept. 1999, Vol. 82, No. 1, pages 27-37).

The claimed invention is drawn to the claimed invention described above wherein the PCR method comprises a fluorescently labeled probe.

The teachings of Handberg and Becker are described above. Neither Handberg nor Becker teaches a PCR using a fluorescently labeled probe.

Burgess et al. (hereinafter Burgess) teaches a quantitative PCR for detecting Marek's disease virus (MDV) using two fluorescent dyes to label one PCR primer of each pair to distinguish the products by colour (Abstract). Burgess teaches the principles used here should be applicable to any cell phenotype and/or cell-associated DNA virus (Abstract).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to fluorescently label the probes. The person of ordinary skill in the art would have been motivated to make that modification because Burgess teaches the products can be distinguished by size and colour, and reasonably would have expected success because Burgess teaches the method is applicable to any cell-associated DNA virus.

#### ***Response to Arguments***

Applicant's arguments will be addressed as they pertain to the new grounds of rejection. Applicants argue "none of the references refer to or suggest axillary tract feathers." Applicants argue Davidson, Handberg and Becker do not "disclose the use of feathers of the axillary tract." The new rejections teach the use of feathers of the axillary tract for the detection of MDV.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Calnek et al. (Avian Diseases, May 1970, Vol. 14, No. 2, pages 219-233) teaches a method of detecting MDV from feathers from the axillary tract (page 221, 2<sup>nd</sup> paragraph).

***Allowable Subject Matter***

Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 9 and 10 are free of the prior art.

***Conclusion***

Due to the new grounds of rejection this action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./  
Primary Examiner, Art Unit 1648

Sharon Hurt

August 7, 2008